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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,281	07/11/2003	Anthony G. Day	GC773-2	4808

7590 09/16/2005

GENENCOR INTERNATIONAL, INC.  
925 PAGE MILL ROAD  
PALO ALTO, CA 94304-1013

EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/618,281

Applicant(s)

DAY ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups 1-92. Claim 1, drawn in part to 92 methods of cleaving a peptide bond in an unspecified protein by contacting the protein with a protease having one of the amino acid sequences set forth in SEQ IDs NOs:1-92, classified in class 435, subclass 68.1.

Groups 93-184. Claims 2-5, drawn in part to 92 methods of identifying a compound that modulates the *in vitro* proteolytic activity of a protease having one of the amino acid sequences of SEQ IDs NOs:1-92, classified in class 435, subclass 23.

Groups 185-276. Claim 6, drawn in part to 92 methods of identifying a compound that modulates the intracellular proteolytic activity of a protease having one of the amino acid sequences of SEQ IDs NOs:1-92 comprising expressing a polynucleotide encoding one of SEQ IDs NOs:1-92 in a cell, classified in class 435, subclass 69.1.

Groups 277-368. Claims 7-16, drawn in part to 92 methods of treating a disease or disorder by administering an unspecified compound that will modulate the activity of a protease having one of the amino acid sequences set forth in SEQ IDs NOs:1-92, classified in class 514, subclass 1.

Groups 369-460. Claim 17, drawn in part to 92 methods of treating a disease or disorder by administering a protease having one of the amino acid sequences of SEQ IDs NOs:1-92, classified in class 424, subclass 94.63.

Groups 461-552. Claim 18, drawn in part to 92 methods of diagnosis comprising contacting a sample with a nucleic acid probe that hybridizes to a polynucleotide encoding one of the protease amino acid sequences of SEQ IDs NOs:1-92, classified in class 536, subclass 24.31.

Groups 553-644. Claim 19, drawn in part to 92 methods of diagnosis comprising conducting a sequence analysis of a portion of a nucleic acid sequence encoding one of the protease amino acid sequences of SEQ IDs NOs:1-92 and comparing that sequence with a reference sequence, classified in class 435, subclass 6.

Groups 645-736. Claim 20, drawn in part to each of at least 92 antibodies capable of binding to a part of protease having one of the amino acid sequences of SEQ IDs NOs:1-92, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-92 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require one of 92

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structurally and functionally distinct proteases in methods that are not disclosed as capable of use together and having different modes of operation and different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 1-92 is not required for another of Groups 1-92, restriction for examination purposes as indicated is proper.

Inventions of Groups 93-184 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require one of 92 structurally and functionally distinct proteases in methods that are not disclosed as capable of use together and having different modes of operation and different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 93-184 is not required for another of Groups 93-184, restriction for examination purposes as indicated is proper.

Inventions of Groups 185-276 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require one of 92 structurally and functionally distinct proteases in methods that are not disclosed as capable of use together and having different modes of operation and different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 185-276 is not required for another of Groups 185-276, restriction for examination purposes as indicated is proper.

Inventions of Groups 277-368 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require one of 92 structurally and functionally distinct proteases in methods that are not disclosed as capable of use together and having different modes of operation and different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 277-368 is not required for another of Groups 277-368, restriction for examination purposes as indicated is proper.

Inventions of Groups 369-460 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

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806.04, MPEP § 808.01). In the instant case the different inventions require one of 92 structurally and functionally distinct proteases in methods that are not disclosed as capable of use together and having different modes of operation and different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 369-460 is not required for another of Groups 369-460, restriction for examination purposes as indicated is proper.

Inventions of Groups 461-552 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require one of 92 structurally and functionally distinct proteases in methods that are not disclosed as capable of use together and having different modes of operation and different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 461-552 is not required for another of Groups 461-552, restriction for examination purposes as indicated is proper.

Inventions of Groups 553-644 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require one of 92 structurally and functionally distinct proteases in methods that are not disclosed as capable of use together and having different modes of operation and different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 553-644 is not required for another of Groups 553-644, restriction for examination purposes as indicated is proper.

Inventions of Groups 645-736 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require one of 92 structurally and functionally distinct proteases in methods that are not disclosed as capable of use together and have different modes of operation and different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 645-736 is not required for another of Groups 645-736, restriction for examination purposes as indicated is proper.

Inventions of Groups 1-92 are unrelated to inventions of Groups 93-184. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

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and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods that are not disclosed as capable of use together and have different functions and different effects.

Inventions of Groups 1-92 are unrelated to inventions of Groups 185-276. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods requiring different starting molecules in order that they may be practiced and are not disclosed as capable of use together and have different functions and different effects.

Inventions of Groups 1-92 are unrelated to inventions of Groups 277-368. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods requiring different starting molecules in order that they may be practiced and are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 1-92 are unrelated to inventions of Groups 369-460. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods that are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

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Inventions of Groups 93-184 are unrelated to inventions of Groups 185-276. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods requiring different starting molecules in order that they may be practiced and are not disclosed as capable of use together and have different functions and different effects.

Inventions of Groups 93-184 are unrelated to inventions of Groups 277-368. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods requiring different starting molecules in order that they may be practiced and are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

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Inventions of Groups 185-276 are unrelated to inventions of Groups 277-368. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods requiring different starting molecules in order that they may be practiced and are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.



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Inventions of Groups 277-368 are unrelated to inventions of Groups 369-460. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods require different products that cannot be structurally or functionally related,

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and the different methods are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

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553-644 are methods of use of products that are not disclosed to be either structurally or functionally unrelated to the antibody products of Groups 645-736 and the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

Because these inventions lack unity and are distinct for the reasons given above, and have acquired a separate status in the art as shown by their different classifications, restriction for examination purposes as indicated is proper.

### *Election*

A telephone call was made to Ms. Victoria Boyd on 13 September 2005 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(h).

### *Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore  
13 September 2005



NASHAAT T. NASHED PHD.  
PRIMARY EXAMINER